Are you eligible?

☐ Do you have a known BRCA1 or BRCA2 mutation?

☐ Are you planning to have surgery to remove your ovaries and fallopian tubes?

☐ Are you premenopausal and willing to use contraception during the study?

☐ Are you willing to take calcium and vitamin D pills for 6 months?

☐ Are you willing to potentially receive 3 or 4 monthly injections of denosumab before your scheduled surgery?

☐ Are you willing to consider participating in a study of a medication that may help high-risk women prevent breast and ovarian cancer in the future?

If you answered YES to these questions, you may be able to join the study.

Contact us

If you want more information, or wish to participate in this study, please contact our study coordinator:

Study Coordinator: Margaret Merrill

By telephone: 617-582-8026

By email: MargaretS_Merrill@dfci.harvard.edu

Principal Investigators:
Judy E. Garber, MD, MPH
Meghna S. Trivedi, MD
Katherine D. Crew, MD MS

This trial is being conducted at:
- Columbia University Medical Center, New York, NY
- Weill Cornell Medical Center, New York, NY
- Dana-Farber Cancer Institute/Brigham and Women’s Hospital, Boston, MA
- Moffitt Cancer Center, Tampa, FL
- Tel Aviv Medical Center, Tel Aviv, Israel

ClinicalTrials.gov [NCT03382574]
What is denosumab?

- Denosumab is an FDA-approved injectable medication that is used to treat osteoporosis and to prevent fractures in cancer patients with bone metastases.

- Some of the most common side effects of denosumab include nausea, tiredness, shortness of breath and low levels of phosphate in the blood.

- There is a study being planned in Europe to determine if long-term treatment with denosumab may prevent breast cancer in BRCA1 mutation carriers.

What are the study groups?

- You will be randomly assigned (meaning by chance or like tossing a coin) to one of two groups. Neither you nor your doctor will decide which group you are in.

- Group 1 (denosumab): 3 or 4 injections of denosumab before surgery; calcium and vitamin D by mouth

- Group 2 (no injection): calcium and vitamin D by mouth. This group is as necessary to understand the effects of denosumab in the group who will receive the injections.

What is involved?

Group 1 (denosumab) and Group 2 (no injection):

- You will have surgery as planned to remove your ovaries and fallopian tubes about 3 to 4 months after starting the study. Leftover tissue from your surgery will be used for research purposes.

- You will need to return for clinic visits about 9 months and 12 months after starting the study for bloodwork and to check for side effects.

For Group 1 (denosumab) participants only:

- You will receive 3 or 4 monthly injections of denosumab before your scheduled surgery.

- You will have a blood draw and pregnancy test before each injection.

This trial is funded by the National Cancer Institute and coordinated by M.D. Anderson Cancer Center.

Denosumab is being provided by Amgen®.